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5 UNITED STATES DISTRICT COURT
6 NORTHERN DISTRICT OF CALIFORNIA

7
8 UNITED STATES OF AMERICA, *ex. rel.* No. C-11-0941 EMC
CAMPIE *et al.*,

9 Plaintiffs,

10 v.

11 GILEAD SCIENCES, INC., *et al.*,

12 Defendants.

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**ORDER GRANTING DEFENDANT'S
MOTION TO DISMISS**

(Docket No. 128)

Relators Jeff and Sherilyn Campie filed this lawsuit against Defendant Gilead Sciences, Inc., asserting, *inter alia*, that it violated federal and state law by submitting or causing to be submitted false claims for payment under government payment programs such as Medicare and Medicaid. In December 2014, the Court granted Gilead's motion to dismiss Relators' first amended complaint ("FAC"), largely because they had failed to plead an actionable misrepresentation as part of the government payment process, but gave Relators leave to amend. Relators then filed their second amended complaint ("SAC") which is now the subject of the pending motion to dismiss.

I. FACTUAL & PROCEDURAL BACKGROUND

A. Claims Asserted

In the SAC, Relators have asserted the following claims against Gilead:

- (1) Count 1: Violation of the False Claims Act ("FCA"), which imposes liability on a person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).

- 1 (2) Count 2: Violation of the FCA, which also imposes liability on a person who “knowingly
2 makes, uses, or causes to be made or used, a false record or statement material to a false or
3 fraudulent claim.” *Id.* § 3729(a)(1)(B).
- 4 (3) Counts 3-28: Violation of the law of twenty-six states or localities, which generally impose
5 liability on false claims for payment.
- 6 (4) Count 29: Retaliation in violation of the FCA. *See id.* § 3730(h) (providing that “[a]ny
7 employee . . . shall be entitled to all relief necessary to make that employee . . . whole, if that
8 employee . . . is discharged, demoted, suspended, threatened, harassed, or in any other
9 manner discriminated against in the terms and conditions of his employment because of
10 lawful acts done by the employee . . . in furtherance of an action under this section or other
11 efforts to stop 1 or more violations of this subchapter [31 U.S.C. § 3721 *et seq.*]”).
- 12 (5) Count 30: Whistleblower retaliation in violation of California Labor Code § 1102.5.
- 13 (6) Count 31: Retaliation in violation of California Labor Code § 98.6.
- 14 (7) Count 32: Termination in violation of California public policy.

15 As indicated by the above, each count can, in essence, be categorized as either: (1) a false
16 claim cause of action or (2) a retaliation cause of action.

17 B. Facts Related to False Claim Causes of Action

18 With respect to the false claim causes of action, Relators’ main allegations in the SAC are as
19 follows.

20 Gilead manufactures a number of drug products, including those for the treatment of
21 HIV/AIDS. *See SAC ¶¶ 18; see also SAC ¶ 18.* “The [federal] Government and the States pay for
22 the majority of Gilead’s drug products sold within the United States through [their] Government
23 Payment Programs.” SAC ¶ 19.

24 Some government payment programs are “reimbursement” programs (*e.g.*, Medicare,
25 Medicaid, the Department of Defense TRICARE program); others are “direct pay” programs (*e.g.*,
26 the Department of Veterans Affairs and the Federal Bureau of Prisons). *See SAC ¶¶ 2, 24.* Under
27 the government reimbursement programs, Gilead is paid when a claim is submitted by a third party

1 such as a plan participant or sponsor; under the government direct pay programs, Gilead is paid
2 when it submits a claim to the government directly. *See SAC ¶ 24.*

3 Gilead's drug products, for which it has been paid by federal, state, and/or local
4 governments, contain active pharmaceutical ingredients ("API"). The API at issue here is
5 emtricitabine ("FTC"), which is used in several Gilead drug products such as Emtriva, Emtriva Oral
6 Powder, Truvada, and Atripla. *See SAC ¶ 144.*

7 As explained in the SAC, "[g]overnment approval of a new drug product under the FDCA
8 [Food, Drug, and Cosmetics Act] takes two forms: initial and supplemental." SAC ¶ 28. Initial
9 approval [from the Food and Drug Administration ('FDA')] is obtained through a new drug
10 application ("NDA"). *See SAC ¶ 29.* "After an NDA has been approved . . . , drug manufacturers . . .
11 . must furthermore obtain Government approval of a PAS [prior approval supplemental] in the event
12 of a change in the manufacturing process that has a substantial potential adverse effect on the
13 identity, strength, quality, purity or potency of the previously approved NDA drug." SAC ¶ 30.

14 As required by the FDCA, Gilead obtained approval from the FDA for the drug products
15 containing the API. However, subsequently, there were major changes to the drug products that
16 required Gilead to obtain supplemental approval from the FDA. Under the FDCA, this new
17 approval was needed *before* Gilead could distribute the drug products that had been changed. *See*
18 *generally SAC ¶ 144.*

19 For drug products containing FTC, the major change was Gilead's use of a new
20 manufacturing source for the API – *i.e.*, Synthetics China, which was an unregistered, uninspected,
21 and unapproved manufacturing source. According to Relators, Gilead began to use Synthetics China
22 as early as 2006 but failed to get supplemental approval from the FDA with respect to this major
23 change before it began to distribute its drugs products containing FTC manufactured by Synthetics
24 China. *See SAC ¶¶ 145-47, 171.* In October 2008, Gilead eventually did seek supplemental
25 approval through a PAS, but the PAS it submitted contained falsified information. For example, the
26 PAS concealed that Synthetics China had produced contaminated batches of FTC. *See SAC ¶¶ 4,*
27 *148, 163.* Gilead amended its PAS in April 2009 in an attempt to correct this problem. *See SAC ¶¶*

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1 163, 235. In mid-2009 or early 2010, the FDA gave its approval to the amended PAS. *See SAC ¶¶*
 2 168, 235.

3 According to Relators, because of Gilead's failure to get supplemental approval from the
 4 FDA for the major changes to the drug products, the drug products were not approved drugs under
 5 the FDCA, and therefore the drug products were not eligible for payment under the government
 6 payment programs. *See SAC ¶ 152.*

7 C. Facts Related to Retaliation Causes of Action

8 Mr. Campie worked at Gilead from about July 2006 to July 2009. *See SAC ¶¶ 13, 206, 238.*
 9 During this entire period, Mr. Campie was employed as Gilead's Senior Director of Global Quality
 10 Assurance ("QA"). *See SAC ¶ 13.* "Mr. Campie's regular job duties focused on commercial drug
 11 product quality assurance/control issues[,] [but] he was (based on job requirements) expected to
 12 review API submissions as well." SAC ¶ 155.

13 At the time Gilead terminated his employment, Mr. Campie was told that "'heart wasn't in
 14 the job anymore.'" SAC ¶ 238. Mr. Campie maintains that he was actually terminated because

15 he discovered, investigated, and raised concerns over Gilead's release
 16 and distribution (much of it for commercial sale in the United States
 17 and paid for by the Government and the States under the Government
 18 Payment Programs) of tons of contaminated and adulterated API that
 19 had been manufactured at an unregistered and uninspected CMO
 20 [contract manufacturing organization]; that had not properly been
 21 demonstrated to be (and in fact was not) equivalent to FDA-approved
 22 API; that was of substandard strength, quality, purity, potency, safety
 23 and/or efficaciousness; that had been used to submit falsified testing,
 24 data, and statements to the FDA; and that had been used to
 25 manufacture the Affected Drug Products which were not approved
 26 under the FDCA and thus were not eligible for payment under the
 27 Government Payment Programs, causing the submission of false
 28 claims paid by the Government and the States.

SAC ¶ 417. According to Mr. Campie, while his termination was the ultimate retaliation, he was also retaliated against in other ways prior to his termination – *e.g.*, by being harassed, by being demoted, by being stripped of job duties, by being ostracized from the regulatory submission review process, and by being removed from his position on Gilead's Quality Council. *See SAC ¶ 417.*

It appears that Mr. Campie raised concerns about "the integrity of the data being generated to support the release of Gilead drugs" as early as July 2007. SAC ¶ 220. For example, on multiple

1 occasions, including at senior staff meetings (the date of which is not clear from the pleading), “Mr.
2 Campie discussed the contamination and adulteration problems with the API being used by Gilead
3 and, more particularly, with Gilead’s knowing use of falsified data and test results for the express
4 purpose of introducing non-approved and contaminated drugs into commerce.” SAC ¶ 221. In
5 response, “Mr. Campie was told that it was ‘none of his concern.’” SAC ¶ 221. In mid-2008, Mr.
6 Campie was removed as head of the internal Quality Control council that he had been chairing since
7 the time he was hired by Gilead. *See* SAC ¶ 209.

8 In late 2008 (which would appear to be around the time that Gilead submitted its Synthetics
9 China PAS to the FDA), “Mr. Campie was presented with a document . . . authorizing the use of API
10 manufactured by Synthetics China.” SAC ¶ 222. Because he was concerned, Mr. Campie “held
11 multiple meetings with both the commercial operations group and the API procurement personnel in
12 an effort to remind and warn the company that drugs containing API sourced from the unregistered,
13 unlicensed and non-approved Synthetics China plant could not be shipped or otherwise distributed
14 into commerce without violating the applicable laws.” SAC ¶ 222. In January 2009, Mr. Campie
15 held a meeting with Gilead management to discuss the same. *See* SAC ¶ 223.

16 In February 2009, “Mr. Campie participated in the review and approval of a Health Canada
17 submission associated with the use of Synthetics China API.” SAC ¶ 225. According to Mr.
18 Campie, “[d]uring his review, [he] identified failing and inconsistent data which he brought to the
19 attention of Tyler Rodgers (Regulatory Affairs/Canada).” SAC ¶ 225. Subsequently, “Mr. Campie
20 continued to voice strenuous objections” regarding Synthetics China – directing his objections to,
21 among others, his manager. SAC ¶ 226.

22 Thereafter, “Gilead began to selectively circumvent Mr. Campie’s review and effectively
23 removed and excluded him from Gilead’s regulatory review process,” even though he “was
24 supposed to be responsible for commercial quality input on regulatory filings implicating quality or
25 supply issues.” SAC ¶ 227. For example, “Gilead management bypassed Mr. Campie completely
26 on the review of the Synthetics China PAS submissions.” SAC ¶ 227. Furthermore, in February
27 2009, Mr. Campie was told during his annual performance review that “he was ‘not effective in
28 influencing peers’ and should therefore start looking for employment elsewhere.” SAC ¶ 229.

1 In March 2009, Mr. Campie met with Gilead’s Chief Compliance Officer “to discuss the
2 falsified data and test results in the Synthetics China PAS.” SAC ¶ 230. Mr. Campie “threatened to
3 inform the FDA if Gilead continued its fraudulent conduct.” SAC ¶ 230. Subsequently, in April
4 2009, Mr. Campie received an e-mail from the GM of the Gilead San Dimas facility that stated:
5 “Well, at least I won’t have to put up with you much longer.”” SAC ¶ 231.

6 In April 2009, Mr. Campie learned that Gilead was preparing to release and distribute a drug
7 containing another API (ambrisentan) that had been manufactured at an unregistered and
8 unapproved facility. *See* SAC ¶ 232. Mr. Campie instructed that “the batches be removed from the
9 company’s supply chain and placed into quarantine until Gilead received Government approval to
10 place them into the stream of commerce.” SAC ¶ 233. Mr. Campie’s manager “told Mr. Campie
11 that initiating quarantine was not in his job description and stated in no uncertain terms that Mr.
12 Campie had no authority to order one. He then continued to state: ‘If you guys can’t protect product
13 supply, you are of very little use to me.’” SAC ¶ 234. The product was ultimately released back
14 into Gilead’s supply chain. *See* SAC ¶ 234. Shortly thereafter, Gilead decided to amend the
15 Synthetics China PAS that it had submitted to the FDA. *See* SAC ¶ 235.

16 “[O]n June 30, 2009, Mr. Campie was called into a meeting and told he would be terminated,
17 effective July of 2009.” SAC ¶ 238. During this meeting, when Mr. Campie “raise[d] the topic of
18 Gilead’s noncompliant practices, including the problems at Synthetics China,” he was asked: “Who
19 are you working for – the company or the FDA?”” SAC ¶ 238.

20 In July 2009, Mr. Campie met with Gilead’s Legal Department, at which time he was asked
21 to sign a severance agreement containing a provision stating that he would not initiate a FCA claim
22 against Gilead. *See* SAC ¶ 240. “Mr. Campie refused.” SAC ¶ 240.

23 **II. DISCUSSION**

24 A. Legal Standard

25 Under Federal Rule of Civil Procedure 12(b)(6), a defendant may move to dismiss for failure
26 to state a claim for relief.

27 “To survive a motion to dismiss, a complaint must contain sufficient
28 factual matter, accepted as true, to ‘state a claim to relief that is
plausible on its face.’” A claim is facially plausible “when the plaintiff

1 pleads factual content that allows the court to draw the reasonable
 2 inference that the defendant is liable for the misconduct alleged.” The
 3 plausibility standard requires more than the sheer possibility or
 4 conceivability that a defendant has acted unlawfully. “Where a
 5 complaint pleads facts that are merely consistent with a defendant’s
 6 liability, it stops short of the line between possibility and plausibility
 7 of entitlement to relief.” Dismissal under Rule 12(b)(6) is proper only
 8 when the complaint either (1) lacks a cognizable legal theory or (2)
 9 fails to allege sufficient facts to support a cognizable legal theory.

10 *Li v. Kerry*, 710 F.3d 995, 999 (9th Cir. 2013) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79
 11 (2009); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007).

12 B. False Claim Causes of Action – Federal

13 Although Relators’ SAC refers to various theories underlying their FCA causes of action,
 14 their opposition brief makes clear that there are really only two theories at issue: (1) an implied false
 15 certification and (2) a factually false certification. The Court addresses each of these theories in
 16 turn.

17 1. Implied False Certification

18 False claims – or false certifications – to the government can be either legal or factual in
 19 nature. There is a legally false certification when the claimant falsely certifies that it has complied
 20 with a statute or regulation, and that compliance is a condition to government payment (e.g., as
 21 reflected in a statute, rule, regulation, or contract). *See United States ex rel. Hendow v. Univ. of*
22 Phoenix, 461 F.3d 1166, 1171 (9th Cir. 2006); *United States ex rel. Ebeid v. Lungwitz*, 616 F.3d
23 993, 1000 (9th Cir. 2010); see also Harrison v. Westinghouse Savannah River Co., 176 F.3d 776,
24 786 (4th Cir. 1999) (stating that “[a] number of courts in a variety of contexts have found violations
 25 of the False Claims Act when a government contract or program required compliance with certain
 26 conditions as a prerequisite to a government benefit, payment, or program; the defendant failed to
 27 comply with those conditions; and the defendant falsely certified that it had complied with the
 28 conditions in order to induce the government benefit”).

29 Legally false certifications can be either express or implied. There is an express false
 30 certification when there is an actual certification of compliance made by the claimant “as part of the
 31 process through which the claim for payment is submitted.” *Ebeid*, 616 F.3d at 998. There is an
 32 implied false certification when the claimant “seeks and makes a claim for payment from the

1 Government without disclosing that it violated regulations that affected its eligibility for payment.”
2 *United States ex rel. Wilkins*, 659 F.3d 295, 305 (3d Cir. 2011) (emphasis added); *United States ex*
3 *rel. Klein v. Empire Educ. Corp.*, 959 F. Supp. 2d 248, 255 (N.D.N.Y. 2013) (noting that there is “an
4 implied false legal certification theory, where, although the claim for payment does not certify
5 compliance with a statute or regulation on its face, compliance is a prerequisite to payment under the
6 express statutory or regulatory terms”).

7 In its prior decision dismissing Relators’ FAC, the Court acknowledged that Relators had
8 presented an implied false certification theory but found it problematic on various grounds.
9 Notably, the Court indicated that, although reimbursement under, *e.g.*, Medicare and Medicaid was
10 conditioned on the drugs being approved by the FDA, “[h]ere, Gilead had obtained FDA approval of
11 all the drugs in question.” *United States ex rel. Campie*, No. C-11-0941 EMC, 2015 U.S. Dist.
12 LEXIS 1635, at *34 (N.D. Cal. Jan. 7, 2015); *see also id.* at *40-41 (stating that “there is no dispute
13 that the affected drugs at issue in this case were, in fact, ‘approved’ by the FDA”). The fact that
14 Gilead had allegedly engaged in fraud before the FDA in obtaining the FDA’s approval did not
15 negate the fact that the condition for payment – approval by the FDA – had in fact been obtained.

16 In their current papers, Relators now argue that they have made allegations in the SAC which
17 make clear the necessary FDA approval was in fact lacking in the instant case. More specifically,
18 Relators argue that, even though Gilead got approval through the NDA process for the drugs in
19 question, there was, subsequently, a major change to the drug products which, under the FDCA,
20 required Gilead to submit a PAS to the FDA and obtain *new approval* for those changes. As noted
21 above, the major change that Relators point to concerned Gilead’s use of an unapproved
22 manufacturing source: Synthetics China.

23 Although Relators have put at issue in their case various government payment programs
24 (both reimbursement and direct pay), the Court shall focus on Medicare/Medicaid as a representative
25 program, particularly as that is consistent with Relators’ approach in their papers. *See, e.g.*, Opp’n
26 at 5.

- 27 • With respect to Medicaid, 42 U.S.C. § 1396r-8 provides that, “[i]n order for payment to be
28 available under section 1903(a) [42 U.S.C. § 1396b(a)] or under part B of title XVIII [42

1 U.S.C. § 1395j *et seq.*] for covered outpatient drugs of a manufacturer, the manufacturer
 2 must have entered into and have in effect a rebate agreement described in subsection (b) with
 3 the Secretary, on behalf of States . . . , and must meet the requirements of paragraph (5)”
 4 *Id.* § 1396r-8(a)(1) (emphasis added). Thus, under Medicaid, there is payment only where
 5 there is a “covered outpatient drug.” “Covered outpatient drug” is defined in § 1396r-8 as a
 6 drug “approved for safety and effectiveness as a prescription drug under section 505 or 507
 7 of the [FDCA, 21 U.S.C. § 355 or former 357] or which is approved under section 505(j) of
 8 such Act [21 U.S.C. § 355(j)].” *Id.* § 1396r-8(k)(2)(A)(i).

9 • Medicare appears to be consistent with Medicaid. For example, under Medicare, a covered
 10 part D drug means, *e.g.*, “[a] drug that may be dispensed only upon a prescription and that is
 11 described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2) [42 U.S.C. §
 12 1396r-8(k)(2)].” *Id.* § 1395w-102(e).

13 Therefore, as Relators contend, under Medicare/Medicaid, it appears that a condition of payment is
 14 FDA approval.

15 That being said, Relators gloss over *what kind* of FDA approval is required. Section 1396r-
 16 8(k)(2)(A)(i) does not refer to any kind of FDA approval but rather “*approv[al]* for safety and
 17 effectiveness as a prescription drug *under section 505 or 507 of the [FDCA, 21 U.S.C. § 355 or*
 18 *former 357] or which is approved under section 505(j) of such Act [21 U.S.C. § 355(j)].*” *Id.* §
 19 1396r-8(k)(2)(A)(i) (emphasis added). Because § 507 is now repealed, the critical FDA approval is
 20 approval under § 505. But § 505 (21 U.S.C. § 355) concerns only approval for a *NDA*, and not
 21 supplemental approval of a *PAS*. Supplemental approval is covered by a completely different statute
 22 – *i.e.*, § 506a. *See* 21 U.S.C. § 356a(c) (providing that “a drug made with a major manufacturing
 23 change may be distributed only if, before the distribution of the drug as so made, the holder involved
 24 submits to the Secretary a supplemental application for such change and the Secretary approves the
 25 application”). Thus, contrary to what Relators suggest, payment under Medicare/Medicaid is
 26 conditioned only on *NDA* approval, and *not supplemental* approval. Because the only condition for
 27 payment is *NDA* approval, then the alleged failure of Gilead to obtain the necessary supplemental
 28 approval does not preclude eligibility for federal payment. Gilead’s failure to get the needed

1 supplemental approval may lead to other consequences for Gilead; however, it cannot be the basis
2 for a false claim cause of action.

3 The Court also notes that, from a policy perspective, it makes sense that a false claim cause
4 of action cannot be based on a company's failure to get a supplemental approval. In the Court's
5 prior order, it emphasized that it found Relators' earlier position based on fraud before the FDA
6 problematic because,

7 [w]ere the FCA [False Claims Act] construed to allow an FCA claim
8 to be based on misrepresentation and omissions made to the FDA
9 during the FDA approval process, the Court sitting on an FCA case
10 would have to delve deeply into the complexities, subtleties and
11 variabilities of the FDA approval process. Ultimately, to determine
12 materiality under the FCA and the "but-for cause in the chain of
13 causation" analysis advocated by Plaintiff, the Court would have to
14 determine whether the FDA would have in fact approved each drug in
15 question. Given the wide range of administrative responses and action
16 that could have been taken by the FDA (*e.g.*, corrective notices,
17 warnings, plan of remediation, requirement of monitoring), the Court
18 would be tasked not only with determining whether a falsity was
presented to the FDA, but also predicting the institutional response of
the FDA and the ultimate outcome of a specialized and complex
administrative proceeding. Given the range of actions available to the
FDA, this would be a daunting task. The Court is ill-equipped to
make that kind of prediction. Such an inquiry stands in contrast to the
inquiry in a more typical FCA case – determining whether a particular
statement or certification made to the payor agency is in fact false and
material to the decision to pay. Absent a clear directive from
Congress, the Court is unwilling to read into the FCA such an
expansive sweep.

19 *Campie*, 2015 U.S. Dist. LEXIS 1635, at *38-39. A similar policy concern is at work here even with
20 Relators' new position as articulated in its current papers.

21 Payment conditioned on NDA approval is an easy determination that does not require the
22 Court to delve into the complexities of the FDCA regulatory process. NDA approval is required
23 whenever there is a new drug that a company seeks to market and distribute, and either there is NDA
24 approval or there is not. However, supplemental approval is required only where there is a major
25 "manufacturing change" to an already approved drug. *See* 21 U.S.C. § 356a(c) (providing that "a
26 drug made with a major manufacturing change may be distributed only if, before the distribution of
27 the drug as so made, the holder involved submits to the Secretary a supplemental application for
28 such change and the Secretary approves the application"). Thus, if a FCA claimant is arguing – as

1 Relators do here – that supplemental approval was needed but not obtained, the court would be
 2 forced into an evaluation of the FDCA regulatory scheme and into making determinations likely
 3 dependent upon the expertise of the FDA in the first instance – *i.e.*, is the manufacturing change at
 4 issue “major” or not? Indeed, a major manufacturing change could include many areas beyond the
 5 manufacturing facility itself – *e.g.*, the composition of the drug, the processing of the drug, the
 6 packing of the drug, the labeling of the drug, and so forth. *See generally* 21 U.S.C. § 355(b)(1).

7 As a final point, the Court notes that, at the hearing, Relators changed their argument
 8 because of the Court’s analysis above. They contended that, even if *supplemental* approval was not
 9 a condition of payment, *NDA* approval in effect was rendered void once Gilead decided to change its
 10 manufacturing facility to Synthetics China because *NDA* approval was conditioned on the use of the
 11 manufacturing facility identified in the *NDA*. Relators correctly note that, in the *NDA*, a company
 12 must provide, among other things, information about the manufacturing facility to be used:

13 (b) Filing application; contents.

14 (1) Any person may file with the Secretary an application
 15 with respect to any drug subject to the provisions of
 16 subsection (a). Such person shall submit to the
 17 Secretary as a part of the application (A) full reports of
 18 investigations which have been made to show whether
 19 or not such drug is safe for use and whether such drug
 20 is effective in use; (B) a full list of the articles used as
 21 components of such drug; (C) a full statement of the
 22 composition of such drug; (D) a full description of the
 23 methods used in, *and the facilities and controls used*
for, the manufacture, processing, and packing of such
drug; (E) such samples of such drug and of the articles
 24 used as components thereof as the Secretary may
 25 require; (F) specimens of the labeling proposed to be
 26 used for such drug, and (G) any assessments required
 27 under section 505B [21 U.S.C. § 355c].

28 21 U.S.C. § 355 (emphasis added).

29 But nothing in the *NDA* statute, § 355, provides that *NDA* approval is rendered void if a
 30 manufacturing facility changes from that listed in the *NDA*. Indeed, Relators have effectively
 31 conceded that a minor change from the *NDA* approval does not render that approval void *ab initio*.
 32 Furthermore, as Gilead points out, the fact that § 355(e) addresses withdrawal of approval makes
 33 Relators’ contention of void *ab initio* problematic. *See id.* § 355(e) (providing that “[t]he Secretary

1 shall . . . withdrawal approval of an application with respect to any drug under this section if the
2 Secretary” makes certain findings – e.g., if he or she finds “that the application contains any untrue
3 statement of material fact”). That is, given that the legislature specifically provided for *withdrawal*
4 of approval, affirmative steps must be taken to void approval.

5 Accordingly, the Court concludes that, as a matter of law, Relators have again failed to plead
6 a claim for violation of the FCA, at least based on an implied false certification theory. Relators
7 have failed to cite to, e.g., a statute, rule, or regulation that makes payment conditioned on
8 supplemental approval by the FDA (as opposed to NDA approval). Indeed, the statute makes clear
9 that such payment is conditioned on NDA approval, not PAS approval. Because the Court
10 previously gave Relators an opportunity to amend on the FCA claim but Relators have failed to
11 correct the same deficiency, the Court dismisses the implied false certification claim with prejudice.

12 2. Factually False Certification

13 As noted above, Relators have asserted not only a legally false certification theory but also a
14 factually false one. “A claim is factually false when the claimant misrepresents what goods or
15 services that it provided to the government.” *United States ex rel. Wilkins v. United Health Group,*
16 *Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). For example, a certification that a company makes to the
17 government is factually false if it incorrectly describes the goods or services provided or requests
18 reimbursement for goods or services never provided. *See United States ex. rel. Mikes v. Straus*, 274
19 F.3d 687, 697 (2d Cir. 2001).

20 Here, Relators’ claim of factually false certification is based on two different subtheories: (1)
21 that the drugs at issue were nonconforming, *see id.*, because they “were not in fact ‘approved’ by the
22 FDA for distribution in interstate commerce,” and (2) that “a drug product not approved for
23 marketing by the FDA is . . . ‘effectively’ and ‘for all practical purposes’ worthless” because it
24 “cannot be introduced into interstate commerce” and is “subject to seizure by the government.”
25 Opp’n at 14.

26 Relators’ first subtheory is duplicative of its implied false certification claim. The entire
27 thrust of the implied false certification claim is that Gilead implied that it had obtained FDA
28

1 approval for its drugs (*i.e.*, were conforming) when it sought payment for the drugs. For the reasons
2 stated above, that claim is legally without merit.

3 The second subtheory is problematic as well. To have a factually false certification claim
4 based on worthless services, the services must be *medically* worthless. *See, e.g., United States ex*
5 *rel. Lee v. Smithkline Beecham Clinical Labs.*, 245 F.3d 1048, 1053 (9th Cir. 2001) (“The district
6 court . . . over-looked the allegations . . . that supported a different theory – that SmithKline violated
7 the FCA by seeking and receiving payment for *medically* worthless tests.”) (emphasis added); *see also Mikes*, 274 F.3d at 702 (“An allegation that defendants violated the Act by submitting claims
9 for worthless services is not predicated upon the false certification theory. Instead, a worthless
10 services claim asserts that the knowing request of federal reimbursement for a procedure with no
11 *medical* value violates the Act irrespective of any certification.”) (emphasis added); *Chesbrough v.*
12 *VPA P.C.*, 655 F.3d 461, 468 (6th Cir. 2011) (“If VPA sought reimbursement for services that it
13 knew were not just of poor quality but had *no* medical value, then it would have effectively
14 submitted claims for services that were not actually provided.”) (emphasis in original). In *Mikes*, the
15 Second Circuit emphasized that a worthless services claim is independent of any false certification
16 claim. *See Mikes*, 274 F.3d at 703 (“We agree that a worthless services claim is a distinct claim
17 under the [FCA]. It is effectively derivative of an allegation that a claim is factually false because it
18 seeks reimbursement for a service not provided.”).

19 In the instant case, Relators have made allegations that suggest *reduced* medical value, but
20 have failed to adequately plead *no* medical value at all. In its prior order dismissing the FAC, the
21 Court concluded that there were insufficient allegations of no medical value, *see Campie*, 2015 U.S.
22 Dist. LEXIS 1635, at *48-49 (noting that some of the allegations “touch on the resulting quality of
23 the drug” but these allegations, “while troubling, do not establish that the affected lots or products
24 were not only ‘worth less’ or defective, but truly ‘worthless’ for the purposes for which the drugs
25 were designed”), and, in their papers, Relators have not really pointed to any additional facts that
26 should dictate a different result. The case that Relators cite in their brief, *United States v. Marcus*,
27 82 F.3d 606, 610 (4th Cir. 1996), is not completely on point as, there, the Fourth Circuit focused on
28 the economic value of the drug specifically, and not its medical value, and for purposes of

1 sentencing a defendant in a criminal proceeding. That is an entirely different inquiry from the issue
 2 now before the Court.

3 The Court thus dismisses Relators' FCA claim to the extent it is based on a factually false
 4 certification theory. As above, the dismissal is with prejudice in light of Relators' prior opportunity
 5 to amend but the still-remaining deficiency with the claim.

6 C. Cause of Action for Retaliation – Federal

7 The Court now turns to Mr. Campie's federal retaliation claim, which is also based on the
 8 FCA. The FCA provides in relevant part that

9 [a]ny employee . . . shall be entitled to all relief necessary to make that
 10 employee . . . whole, if that employee . . . is discharged, demoted,
 11 suspended, threatened, harassed, or in any other manner discriminated
 12 against in the terms and conditions of his employment because of
 lawful acts done by the employee . . . in furtherance of an action under
 this section or other efforts to stop 1 or more violations of this
 subchapter [31 U.S.C. § 3721 *et seq.*].

13 31 U.S.C. § 3730(h). Under Ninth Circuit law,

14 [a] plaintiff alleging a FCA retaliation claim must show three
 15 elements: (1) that he or she engaged in activity protected under the
 16 statute; (2) that the employer knew the plaintiff engaged in protected
 activity; and (3) that the employer discriminated against the plaintiff
 because he or she engaged in protected activity.

17 *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1103 (9th Cir. 2008).

18 In its motion to dismiss, Gilead contends that Mr. Campie has failed to adequately allege a
 19 FCA retaliation claim because the allegations in the SAC do not show that (1) Mr. Campie "was
 20 investigating actual false claims for payment," as opposed to "mere regulatory violations," and that
 21 (2) "Gilead had notice of any such protected activity prior to any alleged adverse employment
 22 action." Mot. at 19.

23 1. Investigation of Fraud on the Government

24 As noted above, Gilead argues first that, "[t]o be covered by the False Claims Act, [a]
 25 plaintiff's investigation must concern 'false or fraudulent' claims." *United States ex rel. Yesudian*,
 26 153 F.3d 731, 740 (D.C. Cir. 1998); *see also Eberhardt v. Integrated Design & Constr., Inc.*, 167
 27 F.3d 861, 868 (4th Cir. 1999) (noting the same); *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d
 28 1034, 1051 (N.D. Ill. 1998) (noting that "[m]any courts have interpreted the 'in furtherance of"

language by emphasizing that the employee's activity must be fueled by, or at least somewhat connected to, her employer's fraudulent activity in submitting false claims for payment to the government"). Here, Gilead contends, Mr. Campie was not investigating false claims but rather only violations of the FDCA, *i.e.*, regulatory violations. *See United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, No. 01-10583-DPW, 2003 U.S. Dist. LEXIS 8846, at *32-33 (D. Mass. May 21, 2003) (stating that “[p]rotected activity includes ‘investigating fraud’ with a goal of ‘trying to recover money for the government,’ not simply correcting ‘regulatory problems’”).

Gilead's position is meritorious. In *United States ex rel. Hopper v. Anton*, 91 F.3d 1261 (9th Cir. 1996), the Ninth Circuit considered whether the plaintiff failed to show she was engaged in “furtherance of an action” under the FCA. 31 U.S.C. § 3730(h). The plaintiff was a special education teacher who worked for a school district. She had complained to her superiors that the school district “was failing to comply with federal and state laws regarding the handling of special education children. Specifically, she alleged that the School District conducted Individualized Education Program (‘IEP’) evaluations of potential special education students with special education teachers rather than with the students’ classroom teachers.” *Hopper*, 91 F.3d at 1263. The Ninth Circuit held that the plaintiff had failed to establish she

was engaged in “furtherance of an action” under the FCA [because] the record quite clearly shows Hopper was merely attempting to get the School District to comply with Federal and State regulations. Her numerous written complaints, seventy letters and over fifty telephone calls were all directed toward this end. *She was not trying to recover money for the government; she was attempting to get classroom teachers into IEP evaluation sessions. She was not investigating fraud.* She was not whistleblowing as envisioned in the paradigm *qui tam* FCA action. Quite plainly, the thrust of her complaints was that the School District was failing to meet its IDEA obligations to its students. Correcting regulatory problems may be a laudable goal, but one not actionable under the FCA in the absence of actual fraudulent conduct.

Id. at 1269 (emphasis added).

The analysis in *Hopper* is on point. While, arguably, Mr. Campie was unlike the plaintiff in *Hopper* because he was in fact investigating fraud, the bottom line is that the fraud with which he was concerned was fraud on the FDA, an agency tasked with ensuring the safety and effectiveness

1 of drugs. Nothing in the SAC indicates that Mr. Campie was concerned about fraud on the
2 government as it relates to money being improperly paid to Gilead by the government.

3 In his opposition, Mr. Campie argues that *Hopper* actually weighs in his favor because, in
4 the case, the Ninth Circuit also stated that “the plaintiff must be investigating matters which are
5 calculated, *or reasonably could lead*, to a viable FCA action.” *Id.* (emphasis added). Presumably,
6 Mr. Campie’s argument is that his investigation of the FDA problems would reasonably lead to a
7 viable FCA action because, without FDA approval, Gilead could not sell its drugs and Gilead’s
8 major customers in the United States are the federal and state/local governments. *See, e.g., SAC ¶*
9 19 (alleging that “[t]he Government and the States pay for the majority of Gilead’s drug products
10 sold within the United States through the Government Payment Programs”).

11 The problem for Mr. Campie is that he has misconstrued the Ninth Circuit’s use of the
12 language “reasonably could lead.” “Reasonably could lead,” as that term was used in *Hopper*, refers
13 to the fact that a FCA retaliation claim may be viable *even if a FCA action is not actually filed*. This
14 was made clear by the Ninth Circuit’s citation to *Neal v. Honeywell Inc.*, 33 F.3d 860 (7th Cir.
15 1994), and *Robertson v. Bell Helicopter Textron*, 32 F.3d 948 (5th Cir. 1994). As the Fifth Circuit
16 stated in *Robertson*, “in *Neal*, the [Seventh Circuit] explained that the *actual filing* of a qui tam suit
17 should not be a prerequisite to protection under § 3730(h).” *Id.* at 951 (emphasis added).

18 Moreover, even if the “reasonably could lead” language could be read along the lines
19 suggested by Mr. Campie, he still would not prevail. That the FDA problems could lead or even
20 would likely lead to a FCA suit does not mean that Mr. Campie’s concern in investigating was false
21 claims; rather, his concern about fraud on the FDA could well have been related to, *e.g.*, public
22 safety issues rather than payment issues. *Cf. Boyd v. Accuray, Inc.*, 873 F. Supp. 2d 1156, 1164
23 (N.D. Cal. 2012) (Koh, J.) (noting that “the record quite clearly shows that Plaintiff was merely
24 attempting to get Accuray to comply with FDA’s ‘traceability’ regulatory requirement and was
25 concerned about patient safety, not fraud against the U.S. government”); *see also United States ex*
26 *rel. Kennedy v. Aventis Pharm., Inc.*, No. 03 C 2750, 2008 U.S. Dist. LEXIS 11904, at *7 (N.D. Ill.
27 Feb. 11, 2008) (rejecting plaintiff’s FCA retaliation claim even though she had alleged her employer
28 had improperly promoted a product for a use other than its FDA-approved use because “[t]he

1 Seventh Circuit has made it clear that an employee's complaints about internal improprieties or
2 violation of federal regulations do not amount to FCA-protected activity"). In this regard, *Iqbal* is
3 instructive – *i.e.*, here, Mr. Campie has simply made allegations that are “merely consistent with”
4 an investigation into false claims, but consistency is not enough to get into the realm of plausibility,
5 *i.e.*, that his motive related to an FCA violation, rather than a general public safety concern vis-a-vis
6 the FDA. *Iqbal*, 556 U.S. at 678.

7 2. Notice

8 For the reasons stated above, dismissal of the FCA retaliation claim is appropriate. The
9 Court, however, also concludes that there is an independent reason to dismiss the retaliation cause of
10 action. More specifically, as Gilead argues, the FCA retaliation claim is problematic because there
11 are insufficient allegations that Gilead knew Mr. Campie was engaging in any activity protected by
12 the FCA. *See Hopper*, 91 F.3d at 1269 (stating that, “unless the employer is aware that the
13 employee is investigating fraud, the employer could not possess the retaliatory intent necessary to
14 establish a violation of § 3730(h)”). As noted by the D.C. Circuit, “the kind of knowledge the
15 defendant must have *mirrors the kind of activity in which the plaintiff must be engaged.*” *Yesudian*,
16 153 F.3d at 742 (emphasis added). If Mr. Campie only notified Gilead about FDA violations, then
17 Gilead would not thereby know that false claims to the government were also an issue. The Court
18 acknowledges Mr. Campie’s allegation that, post-termination, Gilead asked him to sign a severance
19 agreement which included a provision stating that he would not bring a FCA claim. *See* SAC ¶ 240
20 (“Gilead . . . asked Mr. Campie to sign a severance agreement in which he would agree not to
21 initiate a FCA claim[] against Gilead, [thus] confirming Gilead’s awareness that Mr. Campie
22 reasonably believed – and had communicated to Gilead his belief – that Gilead was committing a
23 fraud against the Government.”). But this allegation, by itself, is not sufficient to give rise to a
24 plausible inference of knowledge on the part of Gilead of an impending FCA claim. Mr. Campie did
25 not allege that his severance agreement was unique in including a waiver of any FCA claim. *See*
26 Mot. at 21 (arguing that “generalized or boilerplate releases encompassing a litany of claims against
27 a former employer are utterly inadequate to show notice of false claims activity”). Mr. Campie’s
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1 reliance on *Mendiondo* is unavailing as, there, the plaintiff specifically alleged that she complained
2 to her employer about “false billing and reimbursement practices. *Mendiondo*, 521 F.3d at 1100.

3 Furthermore, there is, as Gilead asserts, another basis for concluding that there are
4 insufficient allegations of knowledge – more specifically, because it was part of Mr. Campie’s “job
5 to investigate and internally report on the alleged FDA regulatory matters at issue.” Mot. at 20-21.
6 Gilead cites in support of this argument *United States ex rel. Ramseyer v. Century Healthcare Corp.*,
7 90 F.3d 1514 (10th Cir. 1996). There, the complaint simply alleged that

8 plaintiff advised her superiors that defendants were not complying
9 with the minimum program requirements of Medicaid. Yet plaintiff
10 never suggested to defendants that she intended to utilize such
11 noncompliance in furtherance of an FCA action. Plaintiff gave no
12 suggestion that she was going to report such noncompliance to
13 government officials, cf. *Clemes*, 843 F. Supp. at 596; *Neal*, 33 F.3d at
14 861, nor did she provide any indication that she was contemplating her
15 own qui tam action. Rather, the monitoring and reporting activities
16 described in plaintiff’s complaint were exactly those activities plaintiff
17 was required to undertake in fulfillment of her job duties, and plaintiff
18 took no steps to put defendants on notice that she was acting “in
furtherance of” an FCA action – e.g., that she was furthering or
intending to further an FCA action rather than merely warning the
defendants of the consequences of their conduct. See *Robertson*, 32
F.3d at 951-52 (contract administrator’s investigation into
overcharging was part of employee’s job and could not have put
employer on notice); *X Corp. v. Doe*, 816 F. Supp. 1086, 1095-96
(E.D. Va. 1993) (lawyer’s discussion of employer’s potential qui tam
liability was part of his job and, because lawyer did not indicate that
he might bring such an action, employer was not on notice).

19 *Id.* at 1523; see also *Eberhardt*, 167 F.3d at 868 (“hold[ing] that an employee tasked with the
20 internal investigation of fraud against the government cannot bring a [FCA] action for retaliation
21 unless the employee puts the employer on notice that a *qui tam* suit under section 3730 is a
22 reasonable possibility”); *Robertson*, 32 F.3d at 952 (stating that “the record contains no evidence
23 that Robertson expressed any concerns to his superiors other than those typically raised as part of a
24 contract administrator’s job”).

25 In his opposition, Mr. Campie does not really challenge the general legal principles
26 articulated in *Ramseyer*. Instead, he argues that, as alleged in the SAC, the investigative activity in
27 which he engaged went well beyond his job duties or description, and therefore Gilead had notice.

1 The problem for Mr. Campie is that the SAC contains conflicting allegations about his duties
2 as a QA director. For example, in the SAC, Mr. Campie does allege: “Mr. Campie’s investigation
3 [of Gilead’s use of Synthetics China as a source of FTC] was not within the typical scope of his
4 normal job duties because, as alleged above, Mr. Campie’s job function concerned commercial
5 quality assurance (the quality of finished job product) as opposed to the ongoing quality of API or
6 other drug ingredients.” SAC ¶ 157. But just two paragraphs before that, Mr. Campie alleges:
7 “[W]hile Mr. Campie’s regular job duties focused on commercial drug quality assurance/control
8 issues[,] *he was (based on job requirements) expected to review API submissions as well.*” SAC ¶
9 155 (emphasis added); *see also* SAC ¶ 225 (alleging that “Mr. Campie participated in the review and
10 approval of a Health Canada submission associated with the use of Synthetics China API”).

11 Furthermore, contrary to what Mr. Campie argues, ¶ 234 of the SAC is not particularly
12 helpful to his position. There, Mr. Campie alleges his manager told him “initiating quarantine was
13 not in his job description” and that he “had no authority to order one.” SAC ¶ 234. But even if Mr.
14 Campie had no specific authority to order a quarantine, that does not detract from the allegation in ¶
15 155 (see above) that part of his job duties was to review API submissions.

16 Moreover, to the extent Mr. Campie argues that Gilead was on notice of his engagement in
17 protected activity because he reported “outside the chain-of-command and beyond Gilead’s
18 corporate complaint resolution process,” Opp’n at 26, nothing in the SAC adequately establishes
19 such. That Mr. Campie talked to people other than his direct manager and people in other groups
20 within Gilead is not enough to lead to a reasonable inference that he was thereby intending to go
21 outside the chain of command, particularly when there are no allegations about what exactly the
22 chain of command was.

23 Finally, to the extent Mr. Campie argues that, at the very least, he was clearly acting outside
24 of his job duties when he threatened to report Gilead’s actions to the federal government, the SAC
25 indicates that he threatened to report to the FDA specifically, and not, e.g., CMS (the payor agency
26 for Medicare and Medicaid). *See* SAC ¶ 230 (“Mr. Campie made clear that he expected Gilead to
27 stop its deceptive practices and threatened to inform the FDA if Gilead continued its fraudulent
28 conduct.”). Thus, this gets Mr. Campie back to the issue of whether giving Gilead notice of a FDA

1 problem would necessarily have alerted Gilead to a FCA problem. *Cf. Eberhardt*, 167 F.3d at 868
 2 (“hold[ing] that an employee tasked with the internal investigation of fraud against the government
 3 cannot bring a [FCA] action for retaliation unless the employee puts the employer on notice that a
 4 *qui tam* suit under section 3730 is a reasonable possibility”). As alleged, it did not.

5 Accordingly, the Court dismisses the FCA retaliation claim. As above, the dismissal is with
 6 prejudice in light of the fact that the Court previously gave Mr. Campie leave to amend and the
 7 claim as now pled is still deficient.

8 D. State Claims

9 Because the Court is dismissing the federal causes of action described above, the only claims
 10 remaining are all based on state law (either false claims or retaliation). The Court declines to
 11 exercise supplemental jurisdiction over the state law claims, especially as this case has not advanced
 12 beyond the pleadings. *See* 28 U.S.C. § 1337(c)(3) (providing that a district court “may decline to
 13 exercise supplemental jurisdiction over a claim . . . if . . . the district court has dismissed all claims
 14 over which it has original jurisdiction”); *see also Sanford v. MemberWorks, Inc.*, 625 F.3d 550, 561
 15 (9th Cir. 2010) (stating that, “[i]n the usual case in which all federal-law claims are eliminated
 16 before trial, the balance of factors to be considered under the pendent jurisdiction doctrine – judicial
 17 economy, convenience, fairness, and comity – will point toward declining to exercise jurisdiction
 18 over the remaining state-law claims”)).

19 **III. CONCLUSION**

20 For the foregoing reasons, the Court grants Gilead’s motion to dismiss. The federal claims
 21 are dismissed with prejudice. The Court declines to exercise supplemental jurisdiction over the state
 22 claims and therefore those claims are dismissed without prejudice.

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1 The Clerk of the Court is instructed to enter judgment in accordance with this opinion and
2 close the file in this case.

3 This order disposes of Docket No. 128.

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5 IT IS SO ORDERED.

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7 Dated: June 12, 2015

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EDWARD M. CHEN
United States District Judge

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